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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,348	08/09/2001	Ramaswamy Murari	DEL-059	4374

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,348	MURARI ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2003 (paper no.5)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Status of the Application

Receipt is acknowledged of the Response filed 02/25/03.

Claims 1-16 are pending. Claims 1-16 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 8 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiang et al. (US Pat. No. 5,252,334).

Chiang discloses a solid matrix system for transdermal drug delivery for administering at least one steroid wherein the device consists of a first layer laminated to a second layer, wherein the first layer consists of a backing material layer and the second layer consists essentially of a therapeutically effective amount of at least one steroid drug and an adhesive matrix which permits high delivery rates for drugs and comprises various polymers. The device, as shown in Fig. 2 includes in addition to the matrix and backing layer, a drug reservoir, wherein the reservoir contains carriers and

surfactants (see reference column 5, line 26 through col. 6, line 28) and claims. The reference meets the requirements of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* (WO 99/63972) in view of Jain et al. (US Pat. No. 5,716,609).

Chen teaches a pharmaceutical unit dosage or unit diagnostic form comprising an active ingredient, a substrate and a deposit that is disposed on the substrate and a

cover layer that overlies the deposit and is joined to the substrate by a bond that encircles that deposit, thereby encapsulating it between the substrate and cover substrates. The deposit comprises a powder, at least some of which includes the at least one active ingredient. The unit form is created via a dry powder deposition apparatus that electrostatically deposits the powder on the substrate (see abstract and claim 31). Figure 1 demonstrates a product comprising a package that is realized as a strip having an array of unit dosage forms. The strip comprises a substrate and a cover layer, wherein the substrate and cover layer each comprise a substantially planar, flexible film or sheet. In some instances, either the substrate or cover layer includes an array of semi-spherical bubbles, concavities, blisters or depressions that are advantageously arranged in columns or rows (reference page 7, lines 21-28). The substrate and cover layer comprise a thermoplastic material. Materials suitable for use as a substrate and/or cover layer include polyvinyl acetate, hydroxypropylmethylcellulose and polyethylene oxide films (page 7, line 30 through pg. 8, line 5). Chen teaches that the deposits may have a shape that is substantially circular and have a size in the range of about 3 mm to about 10 mm (see claim 38). As previously mentioned, the substrate serves as a deposition substrate upon which powder is electrostatically deposited. Further materials suitable for a base substrate can be ethyl cellulose, cellulose acetate phthalate, water-insoluble acrylic copolymers, paper, cross-linked poly(vinyl pyrrolidone), cross-linked gelatin and non-woven fabric (pg. 46, lines 1-11). Figure 48 depicts a substrate comprising a bi-layer film that includes a hydrophobic and hydrophilic layer (figure drawings pg 24/25). In addition,

adhesives may be used for bonding the substrate layer and cover layer together, and for bonding various overcoat/overwrap layers to other layers (pg. 50, lines 14-23).

Chen is deficient only in the sense that he does not explicitly teach a dissolution-enhancing amount of a surfactant.

Jain et al., while teaching a hydrophobic drug (nimesulide) in a transdermal formulation, teaches a percutaneous enhancing vehicle base that comprises percutaneous enhancer(s), surfactant(s), gelling agents/thickeners, one or more vehicle/base, wherein suitable surfactants include hydrophilic or lipophilic surfactants, reacted products of natural and hydrogenated vegetable oils and ethylene glycol, sorbitan fatty acid esters and the like (see reference column 2, line 35 through col. 4, line 43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to be motivated to use surfactants within the pharmaceutical formulation of Chen because Jain explicitly teaches a hydrophobic-drug containing transdermal formulation comprising a percutaneous enhancing vehicle that includes one or more surfactants and percutaneous enhancers wherein the percutaneous enhancing vehicle base serves to act as a microcarrier preconcentrate or a microcarrier and similarly Chen teaches a pharmaceutical formulation comprising active ingredients, such as drugs, for the transdermal delivery of active agents. The expected result would be an improved formulation for the delivery of hydrophobic drugs.

Response to Arguments

Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

May 16, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600